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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,715

04/02/2004

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2515

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EXAMINER

LOVE, TREVOR M

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,715	Applicant(s) PENG ET AL.	
	Examiner TREVOR M. LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/17/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made to applicant's terminal disclaimer with application number 10/717,528 filed 06/17/2008. Acknowledgement is also made to applicant's amendment which removed the trademark HYDROTHANE and replaced it with "hydrophilic polyurethane".

Claims 1-19 are pending.

Double Patenting

The **provisional non-statutory double patenting rejection of claims 1-19** presented 03/18/2008 has been **withdrawn** in light of the terminal disclaimer filed 06/17/2008.

Claim Rejections - 35 USC § 112

The **rejections based on 35 USC § 112 of claims 4, 7-10, 12-14, and 16-18** presented 03/18/2008 have been **withdrawn** in light of applicant's amendment filed 06/17/2008. The removal of the trademark HYDROTHANE resolved the indefiniteness associated with the use of trademarks within claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference (Turner) has two common inventors with the instant application (Martineau and Shek). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of

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the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,331,578 (Turner) in light of U.S. Patent No. 4,396,377 (Roemer) is maintained.

Turner discloses a method of making an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the mixture forms a membrane (Turner, column 9, lines 11-14). Turner does not disclose the use of aging, however, Roemer does disclose the use of aging on an IPN to insure that the crosslinked polymer has become substantially interpenetrated (Roemer, column 12, lines 53-57). It would be obvious to one of ordinary skill in the art to allow the IPN of Turner to age to increase the amount of crosslinking that occurred.

Turner further discloses that the hydrophobic component is a siloxane, as in instant claim 4 (Turner, column 11, line 13-15), and the reaction mixture of the above

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components also has a crosslinker as required in claim 2 (Turner, column 22, lines 55-58). Turner further discloses that the membrane, which is an elastomeric polymer network, has the ability to expand and retract based on the environment (Turner, column 10, lines 56-60), and is thus a three-dimensional open mesh as specified in claim 3. Also, Turner further discloses that the hydrophilic component is polyethylene oxide (Turner, column 11, lines 43-46).

Turner does not disclose aging, or the addition of heat as in claim 5, however Roemer in referring to aging, further discloses that the application of heat is usually required for curing (Roemer, column 12, lines 29-31). It would be obvious to use the aging and heating of Roemer to create a more interpenetrated polymer network.

Applicant's Arguments

Applicant argued that Roemer does not teach the limitations of instant claim 1, and was therefore, improperly applied. Applicant acknowledges that Roemer teaches the aging of a precursor blend for a period of time sufficient to ensure that the cross-linked polymer has become substantially swollen with, interpenetrated by, or has substantially imbibed the monomer cross-linked agent mixture. Applicant argues that Roemer fails to teach the aging of the first solution of a biocompatible, hydrophilic first component selected from the group consisting of a biopolymer, a synthetic polymer, and monomers and prepolymers of said biopolymer and synthetic polymer. Namely, applicant states that Roemer teaches mixing all the components together, and then allowing the composition to age. Applicant argues that the teaching of aging a precursor blend to promote crosslinking is insufficient to create a prediction that aging a

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first solution of a hydrophilic component and subsequent mixing with a solution of a hydrophobic component will create a good quality IPN.

Response to Arguments

Roemer, while not providing an anticipatory disclosure of instant claim 1, does provide motivation for the shortcomings of Turner. Turner's main shortcomings are that the concept of aging the first component is not immediately envisaged, and the addition of heat is not directly disclosed. Turner is teaching the two separate components, one hydrophilic, one hydrophobic (see Turner, column 9, lines 12-23). Furthermore, as evidenced by claim 1 of Turner the first component is crosslinked prior to combination with the second component. Hence, Roemer provides strong motivation for the aging, in that Turner is desiring the first of the two components to be crosslinked, and Roemer teaches that to best achieve crosslinking, it is desirable to allow time sufficient to insure that interpenetration occurs. The examiner is not relying on the blend of Roemer, merely that Roemer is teaching monomers and prepolymer materials to establish a nexus between Turner and Roemer, and that Roemer teaches that allowing monomers and prepolymer components to have "sufficient time" provides superior results.

As evidenced above, applicant's remarks filed 06/17/2008 have been fully considered, but are not found persuasive. The rejection is maintained and made final.

The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over the Turner and Roemer as applied to claim 1, and further in view of U.S. patent 6,268,405 to Yao is maintained.

Turner does not disclose freeze-drying, however, Yao) discloses the freeze-thaw crosslinking method. It would be obvious to one of ordinary skill to use the freeze-thaw method to increase the mechanical strength of the IPN(Yao, column 2, lines 6-7, and 16-18).

The rejection of Claims 7-19 under 35 U.S.C. 103(a) as being unpatentable over Turner and Roemer as applied to claim 1, in further view of U.S. Patent No. 4,966,953 (Shikinami) is maintained.

Turner teaches the disclosure as set forth above but fails to teach polyurethane or gelatin as in claim 7. Shikinami, while teaching a polyurethane gel, discloses that both polyurethane and gelatin are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikinami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin since they can both be crosslinked relatively easily.

Turner further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). Though Turner does not directly teach gelatin, it can be seen from the discussion of Instant Claim 7, specifically concerning the disclosure of Shikinami, it would be obvious to one of ordinary skill in the art to use gelatin as said hydrophilic component, but Turner further shows that a methacrylate, which can include a methacrylate of gelatin, would be even better. Therefore, it would be obvious to one of ordinary skill in the art to create said methacrylate by adding methacrylic anhydride to

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the gelatin which would inevitably create even greater crosslinking within the gelatin as claimed in claim 8. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36).

Roemer discloses the use of aging to increase crosslinking as in instant claims 9-10. The length of the aging taught in Roemer is 1-7 days (see column 13, lines 4-6). It would be obvious to the artisan to adjust the length of the aging to achieve the desired equilibrium and to achieved the greatest amount of crosslinking.

The amount of time and the temperature, as in instant claims 11-12 are disclosed in Roemer and Turner respectively. Roemer teaches, as indicated above, that the aging period is 1-7 days, this time period overlaps with the instant 3-24 days (see Roemer, column 13, lines 4-6). Furthermore, Turner teaches that the crosslinking and polymerization occur at a maintained temperature of approximately 50°C (see Turner, column 14, lines 30-49) . It would be obvious to one of ordinary skill in the art allow for the invention of Turner at 50°C to age for the time period of Roemer in order to achieve superior crosslinking and polymerization.

Turner does not discuss freeze-drying as in claims 13-14. Yao does disclose the freeze-thaw method for the use of increasing the mechanical strength of a hydrogel (Yao, column 2, lines 5-18). The freeze-thaw method is a method wherein the components are frozen and then thawed. This is the same as the freeze drying set forth in Instant Claims 13 and 14 because for the freeze drying to be effective on a hydrogel, it would have to be rehydrated/thawed. Also, the temperature at which the freezing occurred is taught by Yao to be approximately -60°C to -20°C (see column 4, line 40). It

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would be obvious to one of ordinary skill in the art to optimize the range to determine the temperature at which the greatest crosslinking is achieved. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

Turner discloses a method of making an IPN, wherein the two components are hydrophobic and hydrophilic respectively (Turner, column 9, lines 12-13), wherein the hydrophobic component is preferred to be an elastomeric biocompatible polymer (Turner, column 11, lines 11-12), and wherein the hydrophilic component can be polyethylene oxide (Turner, column 11, lines 43-46), which is a biocompatible polymer. Also, the mixture forms a membrane (Turner, column 9, lines 11-14). Turner does not disclose the use of a freeze-drying method as in claim 15. However, Yao does disclose such a method as the freeze-thaw method, the motivation being that it would increase the mechanical strength of the IPN (Yao, column 2, lines 5-18).

Turner goes on to teach the disclosure as set forth above but fails to teach polyurethane or gelatin as in claim 16. Shikinami, while teaching a polyurethane gel, discloses that both polyurethane and gelatin are polymer compounds which can form hydrogels (U.S. Patent 4,966,953, Shikinami, column 1, line 48 – column 2, line 2). It would be obvious to one of ordinary skill in the art to modify Turner by using polyurethane and gelatin since they can both be crosslinked relatively easily. Turner

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further discloses that the hydrophilic component's constituents may be any crosslinkable water soluble polymer, prepolymer, or copolymer. Turner continues on to disclose that methacrylates are one of the preferred options (Turner, column 11, lines 43-48). Though Turner does not directly teach gelatin, it can be seen from the discussion of Instant Claim 7, specifically concerning the disclosure of Shikinami, it would be obvious to one of ordinary skill in the art to use gelatin as said hydrophilic component, but Turner further shows that a methacrylate, which can include a methacrylate of gelatin, would be even better. Therefore, it would be obvious to one of ordinary skill in the art to create said methacrylate by adding methacrylic anhydride to the gelatin which would inevitably create even greater crosslinking within the gelatin. Also, to initiate the crosslinking, it is well known in the art to use UV radiation (Turner, column 1, lines 44-46; column 14, lines 33-36).

The temperature of the freezing process specified in claim 17 would have been obvious to one of ordinary skill in the art particularly since temperature at which the freezing occurred is taught by Yao to be approximately -60°C to -20°C (see column 4, line 40). It would be obvious to one of ordinary skill in the art to optimize the range to determine the temperature at which the greatest crosslinking is achieved. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

Turner does not teach the use of aging, as in claim 18, however, it is disclosed in Roemer to use aging for an IPN to ensure that the crosslinked polymer has become substantially interpenetrated (Roemer, column 12, lines 53-57). It would be obvious to one of ordinary skill in the art to allow the IPN of Turner to age to increase the amount of crosslinking that occurred. The length of the aging would have been obvious to one of ordinary skill in the art at the time the invention was made in order to achieve the greatest amount of crosslinking.

With regards to claims 18 and 19, it would have been obvious to one of ordinary skill in the art at the time the invention as made to desire to have crosslinked methacrylated gelatin. Furthermore, it is disclosed in Roemer, as discussed above, that aging for 1-7 days allows for increased crosslinking. It is known that when a crosslinking environment has been established that higher concentrations will result in a higher number of crosslinks occurring. Furthermore, it would be obvious to dilute the solution to achieve the concentration desired for mixing with the polyurethane. One would have been motivated to have a higher concentration to increase the probability of crosslinking. There would be a reasonable expectation of success since adjusting concentrations and aging are known in the art. With regards to the specific concentrations of the methacrylated gelatin, as evidenced by the examples of Roemer (see examples 1-6), it is well known that varying the specific values of the methacrylated component in a crosslinked composition is within the purview of an

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artisan of ordinary skill. Therefore it would have been obvious to, and within the purview of, one of ordinary skill in the art at the time the invention was made to use an aged concentrated amount of methacrylated gelatin, such as 18%, to allow for an increased amount of crosslinking, and subsequently diluting said composition to the desired amount for mixing with said second component.

No claims are allowed. All claims are rejected. No claims are objected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is

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(571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611